REMARKS

Upon entry of the present Amendments, Claims 1-6 are all the claims pending in the Application. New Claims 3-6 have been introduced. Support for the new claims can be found throughout the specification and originally filed claims.

Specifically, support for new Claim 3 is found at least at page 5, lines 14-20.

Support for new Claims 4 and 5 are found at least at page 14, lines 9-16.

Support for new Claim 6 is found at least at page 5, lines 9-13.

Accordingly, no new matter has been introduced by these amendments.

Present Claims Define Allowable Subject Matter

Claims 1 and 2 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tanaka et al. (Cancer Letters, Vol. 172, pages 119-126) ("Tanaka"), in view of Fan et al. ("Mouse Skin Tumor Assay", 1996, Toxicology and Risk Assessment: Principles, Methods, and Applications, pages 124-127) ("Fan").

Tanaka is relied upon as assertedly teaching the claimed compound and its high anti-tumor promoting activity (Abstract; page 121, compound 1). Various passages of Tanaka are cited including: that compound 1 "is considered to be a naturally occurring triterpenoind with the strongest anti-tumor promoting activity in the in vivo assay ever known" (page 124, last paragraph); that the *in vivo* assay used is a two-stage mouse skin carcinogenesis assay (page 122); that compound 1 is a "promising candidate for effective and safe chemopreventive agents"

(page 125); and that Tanaka does not teach the use of the claimed compound for the treatment of lung tumorigenesis or its oral administration.

Fan is cited as assertedly teaching mouse skin tumor assays and their use as a screening tool for carcinogens and carcinogen promoters. Particularly, Fan is cited as teaching a correlation between the mouse skin tumor assay and the mouse lung adenoma assay as well as the use of the skin tumor assays for pharmacological research on chemotherapeutic agents (pages 124-127).

In view of the foregoing it is asserted that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Tanaka and Fan in order to test the effectiveness of the compound of Tanaka in inhibiting tumorigenesis in other tissues, including the lung. It is further asserted that one of ordinary skill in the art would have been motivated to administer the compound orally for patient convenience and administration compliance.

It is further asserted that the teaching of Fan (of a correlation between the mouse skin tumor assay and the lung adenoma assay) was cited for providing *further* motivation for one of ordinary skill to test the compound for effectiveness in inhibiting lung tumorigenesis. In this regard, Fan was cited to allegedly provide a correlation of carcinogenic activity between the mouse skin tumor assay and the mouse lung adenoma assay (*e.g.*, similar lowest systemic dose having a positive carcinogenic response in both assays).

Applicants respectfully traverse this rejection for the reasons set forth in the Rule 1.111 Response filed May 4, 2009, and for the following additional reasons.

Fan teaches that chemical carcinogenesis in skin is a multistage process (page 124, second full paragraph). Accordingly, the mouse skin carcinogenesis test of Tanaka (section 2.4) and the mouse skin tumor assay of Fan (section 2) are both multi-stage assays. Tanaka teaches a two-stage process including topical treatment with DMBA as an initiating treatment and application of TPA as a promotion treatment (page 122, column 2). Fan teaches a two-stage protocol consisting of an initiation step and a promotion step (page 125, last paragraph) as well as a multi-stage protocol consisting of a further progression step (page 126, second full paragraph).

In contrast, Applicant discloses in, for example, Example 3, tumorigenesis produced by administration of diethylnitrosamine (interperitoneally), N-methyl-N-nitrosourea (interperitoneally), dimethylhydrazine (subcutaneously), N-butyl-N-(4-hydroxybutyl)nitrosamine (ingestion), and 2,2′-dihydroxy-di-n-propylnitrosamine (ingestion). Thus, Applicants submit that a skilled artisan would not apply the compound of Tanaka to suppress or inhibit *lung* tumorigenesis because such tumorigenesis is not known to be a multistage process as taught by Tanaka and Fan.

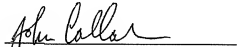
In view of the foregoing, Applicants submit that the present claimed method of treatment for suppressing or inhibiting lung tumorgenesis would not have been obvious from Tanaka and or Fan.

In order to further define the present claimed invention from the cited references Applicants have, as mentioned above added new Claims 3-6 which define over the prior art for the reasons discussed above and because of the additional features recited in the new claims.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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